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10/672,660

09/25/2003

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/672,660

Applicant(s)

THACKER ET AL.

Examiner

Kristen Droesch Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-2, 22-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-51 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 22-24, 26-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 25 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 22-23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley (2003/0093134).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Bradley shows obtaining a stimulation parameter set, providing stimulation to a selected region of a spinal cord in accordance with the stimulation parameter set, obtaining a level of power consumption of the stimulation parameter set, repeating the steps for each of a plurality of different stimulation parameter sets and determining a low power consumption stimulation parameter set based, at least in part, on the levels of power consumption respectively associate with the different stimulation parameter sets (paras. [0013], [0023], [0038], [0042]).

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With respect to claim 2, Bradley shows obtaining the stimulation parameter set comprises selecting one of a multiple of stimulation parameter sets and adjusting the stimulation level of the parameter set to find an adequate stimulation level (therapeutic ratio) for achieving sensory parasthesia (Fig. 5; paras. [0036]-[0038]).

Regarding claim 22, Bradley shows obtaining a level of power consumption comprises computing a value of the power consumption (amplitude times duration) (para. [0038]).

With respect to claim 23, Bradley shows the low power consumption stimulation parameter set is selected from the different stimulation parameter sets (Claim 10).

Regarding claim 26, Bradley shows programming the low power consumption stimulation parameter set into a spinal cord stimulation (SCS) implantable pulse generator (IPG) (para. [0038]).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 27-33 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Mouchawar et al. (6,738,668) in view of Gold (4,444,195).

Regarding claim 27, Mouchawar shows a system comprising: a lead; an electrical pulse generator mated with the lead configured for providing stimulation in accordance with a plurality of different stimulation parameter sets; and a programming device (38) configured for associating levels of power consumption respectively with the different

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stimulation parameter sets, and determining the low power consumption stimulation parameter set based, at least in part, on the levels of power consumption respectively associated with the different stimulation parameter sets (Fig. 10; Col. 12, line 39-Col. 13, line 9). Although Mouchawar fails to show a lead carrying a plurality of electrodes, but rather shows two leads having a single electrode. Gold teaches it is desirable to use a single lead with multiple electrodes in order to avoid the disadvantage of the complicated procedure of placing two separate leads because it is possible to strike the first lead with the second lead thereby dislodging the first lead. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Mouchawar by substituting the two electrodes on separate leads with a single lead having two electrodes since Mouchawar teaches it is desirable to use a single lead with multiple electrodes in order to avoid the disadvantage of the complicated procedure of placing two separate leads because it is possible to strike the first lead with the second lead thereby dislodging the first lead

With respect to claim 28-29, Mouchawar shows an electrode lead coupled to the pulse generator, furthermore, the pulse generator could be used externally.

Regarding claim 30, Mouchawar further shows the programming device is configured for allowing a user to adjust the stimulation levels of stimulation parameter sets (Col. 9, line 13-Col. 13, line 22; Figs. 1, 10).

With respect to claim 31, Mouchawar shows the programming device is further configured for computing the values of power consumption, respectively associating the computed values of power consumption with the different stimulation parameter sets, and determining the low power consumption stimulation parameter set based, at least in part,

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on the values of power consumption respectively associated with the different stimulation parameter sets (Col. 9, line 13-Col. 13, line 22; Fig. 10).

Regarding claims 32-33, Mouchawar shows a user interface (102, 104, 106) (Fig. 1).

With respect to claim 35, Mouchawar shows the programming device is configured for programming.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. Examples of functional language and statements of intended that are not considered to impart any further structural limitations over the prior art are:

- configured for providing stimulation to a selected region of a spinal cord via the electrodes
- spinal cord stimulation (SCS) electrode lead
- external trial stimulator (ETS)
- configured for allowing a user to select the low power consumption stimulation parameter set from the different stimulation parameter sets
- configured for displaying representations of the different stimulation parameter sets and associated levels of power consumption to a user
- configured for programming the low power consumption stimulation parameter set into a spinal cord stimulation (SCS) implantable pulse generator (IPG).

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being obvious over Bradley (2003/0093134) as applied to claim 23 above. Bradley shows the user selecting the low power consumption stimulation parameter, but Bradley fails to show displaying

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representations of the different stimulation parameter sets and associated levels of power consumption to a user, and the user selecting the low power consumption stimulation parameter set from the displayed stimulation parameter set representations. It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Bradley to include displaying representations of the different stimulation parameter sets and associated levels of power consumption to a user and selecting the low power consumption stimulation parameter set from the displayed stimulation parameter set representations in order to make the fitting process easier and more streamlined.

6. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

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7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Response to Arguments

8. Applicant's arguments with respect to claims 27-33 and 35 as rejected over Mouchawar have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments with respect to claims 1, 2, 22, 23, 24 and 26 as rejected over Bradley are not persuasive. Applicants make reference to a declaration filed under 35 USC 1.132 by Kerry Bradley. However, it does not appear that a declaration was actually filed with the USPTO. As a result, the rejection is maintained

Allowable Subject Matter

10. Claims 25 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 36-51 are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kdm

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